PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(date/month/year)* 03 December 2004 (03-12-2004)

Applicant's or agent's file reference	**FOR FURTHER ACTION** See paragraph 2 below
08898491WO	

International application nº	International filing date *(date/month/year)*)	Priority date *(date/month/year)*
PCT/CA2004/001474	16 August 2004 (16-08-2004)	13 August 2003 (13-08-2003)

International Patent Classification (IPC)
Primary: G01N 33/66
Cross references: G01N 33/02, G01N 33/48, G01N 33/74

Applicant CEAPRO INC. ET AL

1. This opinion contains indications relating to the following items :

[X]	Box No. I	Basis of the opinion
[X]	Box No. II	Priority
[X]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[ ]	Box No. VI	Certain documents cited
[X]	Box No. VII	Certain defects in the international application
[X]	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**
If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/	Authorized officer
Commissioner of Patents *Canadian Patent Office* *Box PCT, Ottawa/Gatineau K1A 0C9* Facsimile No. (819) 953-9538	David Boudreau (819) 997-2926

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis o the international application in the language which it was filed, unless otherwise indicated under this item.

[ ] This opinion has been established on the basis of a translation from the original language into the following language __ , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of :

a. type of material

[ ] a sequence listing

[ ] table(s) related to the sequence listing

b. format of material

[ ] in written format

[ ] in computer readable from

c. time of filing/furnishing

[ ] contained in the international application as filed.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority for the purposes of search.

3. [ ] In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments :

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Box No. II Priority

1 [X] The following document has not yet been furnished :

[X] copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

[ ] translation of the earlier application whose priority has been claimed (rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2 [ ] This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purpose of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary :

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of :

[ ] the entire international application

[X] claim No. 24

because

[X] Claim 24 relates to the following subject matter which does not require an international preliminary examination *(specify)* :

The subject matter of claim 24 was not searched since it refers to excluded subject matter under article 17.2 (a)(i) and rule 39(i) and (v). A method of calculating an average, as disclosed in claim 24, refers to a mere presentation of information and a mathematical concept.

[ ] the description, claims or drawings *(indicate particular elements below)* or said claims Nos. ___ are so unclear that no meaningful opinion could be formed *(specify)* :

[ ] the claims, or said claims Nos. ___ are so inadequately supported by the description that no meaningful opinion

[ ] no international search report has been established for said claims Nos. ___.

[ ] the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that :

the written form	[ ]	has not been furnished
	[ ]	does not comply with the standard
the computer readable form	[ ]	has not been furnished
	[ ]	does not comply with the standard

[ ] the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

[ ] See Supplemental Box for further details.

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Box No. IV Lack of unity of invention

1 [ ] In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has :

[ ] paid additional fees

[ ] paid additional fees under protest

[ ] not paid additional fees

2 [ ] This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3 This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

[ ] complied with

[ ] not complied with for the following reasons :

4 Consequently, this opinion has been established in respect of the following parts of the international application :

[ ] all parts

[ ] the parts relating to claims Nos. ____

Box No. V reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

A. Novelty (N)	Claims	1-23	YES
	Claims	NA	NO
B. Inventive step (IS)	Claims	1-23	YES
	Claims	NA	NO
C. Industrial applicability (IA)	Claims	1-14, and 21-22	YES
	Claims	15-20, and 23	NO

2. Citations and explanations :

D1: WO9702050
D2: Jenkins et al. (2002). *Eur. J. Clin. Nutr.* **56**(7): 622-628.

A. Novelty
The subject matter of the alleged invention differs from the closest prior art (D1), in that the diagnostic test meal of the present invention contains a low soluble fibre content (less than 0.5 wt. %), whereas D1's diagnostic test meal contains about 1.5 wt. % of soluble fibre. Therefore, the claims on file comply with article 33.2 of the *Patent Cooperation Treaty (PCT)*.

B. Inventive step
Claim 1, which is novel, is also non-obvious. The closest prior art (D2) relating with soluble fibre and glucose absorption, would not lead a skilled person in the art to design a diagnostic test meal containing less than 0.5 w.t % of soluble fibre. Therefore, the claims on file comply with article 33.3 of the *Patent Cooperation Treaty (PCT)*.

C. Industrial applicability
Claims 15-20 and 23 do not have an industrial applicability as defined under article 33.4 of the *Patent Cooperation Treaty (PCT)*. Although both claims specified utility by indicating how useful the methods may diagnose a given disorder, they both failed to indicate how the diagnosing step would be performed. The dependent claims 16-20, which depend on claim 15, do not add an industrial applicability.

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted :

Claim defects

Claim 1 does not comply with article 6 of the *Patent Cooperation Treaty (PCT)*. An independent claim should clearly specify all the essential features needed to define the invention. It appears that the following feature (below), indicated in the description, would be essential to the performance of the alleged invention. This feature should be incorporated in the above claim.

"[The diagnostic test meal provides] a selected quantity of glycemic carbohydrate ..." (page 19, lines 1-4).

The claims on file lack clarity (article 6 of the *Patent Cooperation Treaty*) and are inconsistent (rule 10.2 of the *Regulations under the PCT*).

- From the wording of the claims 4, 8 and 9, it is understood that mono- and disaccharides would not represent glycemic carbohydrates, since the prefix "glycemic" is not utilized. However, from the reading of the description, the expression "glycemic carbohydrate" is defined as glucose or a complex carbohydrate, which can be metabolized or reduced to glucose. Both glucose (monosaccharide) and sucrose (disaccharide) contain glucose, and could therefore be associated to the expression "glycemic carbohydrate". Hence, the expression "glycemic carbohydrate" is unclear.
- Claims 1 and 14 refer to the term "polysaccharide", which is inconsistent with claims 4 and 11, which refer to the expression "glycemic polysaccharide".

Claims 15 and 23 do not comply with article 6 of the *Patent Cooperation Treaty (PCT)*. The above claims are incomplete and are silent on essential features needed to define the invention.

- Claim 15 refers to a method of diagnosing a disorder of carbohydrate metabolism in a vertebrate subject. Claim 15 is incomplete being silent on how the diagnosing step is performed and fails to provide at which time the blood sample is taken for the glucose concentration measurement.
- Claim 23 refers to a method of diabetes self-diagnosis and self-monitoring in a vertebrate subject. Claim 23 is incomplete being silent on the comparison step (comparing the obtain glucose concentration with a reference value), and how the diagnosing and monitoring steps are performed. Claim 23 also fails to provide when the blood sample is taken after ingestion, for glucose concentration measurement.

Claims 11 and 15 do not comply with article 6 of the *Patent Cooperation Treaty (PCT)*. The following expressions have no antecedent, which render the scope of the claims unclear:

"glycemic polysaccharide" (claim 11, lines 7-8), when dependent on claims 1-3;
"biological sample" (claim 15, line 29), when dependent on claims 1-14.

Note to the applicant:
The expression "biological sample" (claim 16, line 33) have already been defined in claim 15, and should therefore be referred to using a definite article to avoid double inclusion.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made :

Description defects

The description encompasses a discrepancy and does not comply with article 5 of the *Patent Cooperation Treaty (PCT)*. The reference "Haber et al." (page 4, line 32) is not clearly identified in such a manner that the document could be easily retrieved.